MEDICAL DIAGNOSTECH

# Covid-19 Story: Challenges & Opportunities for IVD Developers

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# Company Background

- Medical Diagnostech (Pty) Ltd was established in 2010 as a developer and manufacturer of lateral flow rapid diagnostic test kits.
- We manufacture high quality rapid diagnostic test kits, using our trade secret methodology for increased sensitivity and early detection.

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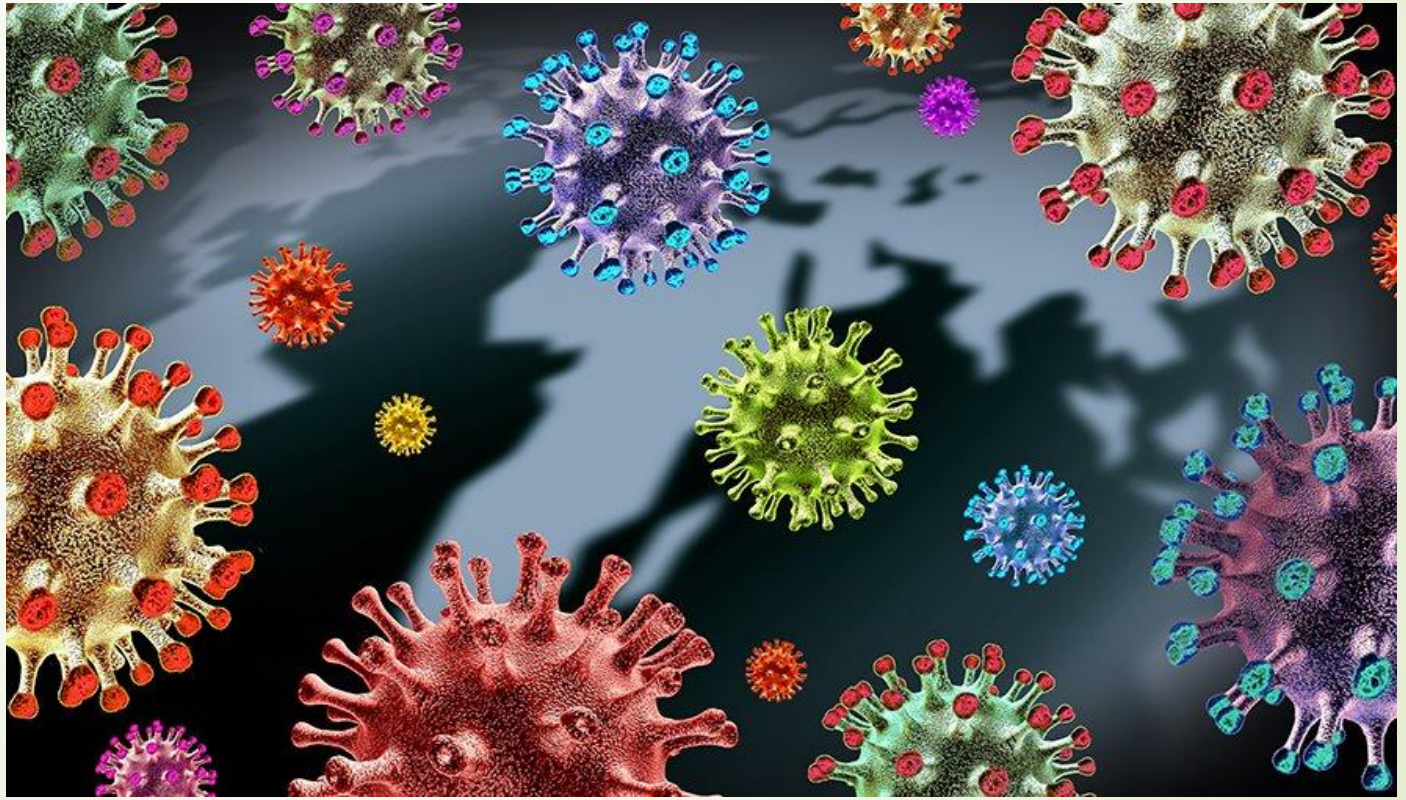
# Complete Global Disruption 2020



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# CHALLENGES?

- 1. Development
- 2. Regulatory Approval
- 3. Marketing

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# 1. Development

- Getting COVID positive samples
  - Because the virus was new, no institutions were willing to share samples, especially if you did not have ethical clearance
- Thus, we had to first obtain ethical clearance and a GCP certificate to engage with hospitals and patients
- Delays in logistics impacted existing production
- Not enough local funding made available for development

# 2. Regulatory Approval

- Initial communication was poor with SAHPRA (however, this improved in late 2021)
- Mis-communication between SAHPRA and the NRL.
  - The NRL validates IVDs on behalf of SAHPRA for regulatory approval
- The costs of IVD validation at the NRL was very expensive and slow
- No home testing allowed
- Slow regulatory reaction impacted viral spread

SAHPRA
South African Health Products Regulatory Authority

# 3. Marketing

- Our Covid-19 Antigen test was only approved by SAHPRA in December 2021

# IF HINDSIGHT WAS 20/20

- SAHPRA has only begun to enforce the need for manufacturing companies to apply for a validation license at an NRL in the last three years
  - Covid pandemic caused a lot of confusion
- SAHPRA requirements for IVD product marketing for public tender market keeps changing
  - First they communicated that locally manufactured IVDs only needs SAHPRA approval
  - Next they communicated that WHO-PQ is also a requirement
- The goal posts for local manufacturers keep shifting
  - Making it difficult to take part in the supply of IVDs
- Foreign products flooded the market due to non-existent import tariffs or duties
  - Zero market localization had a negative impact on local companies

# RECOMMENDATIONS

- NRAs should re-evaluate approval of locally manufactured products vs imported product
  - WHO-PQ requirements on top of SAHPRA approval?
  - However, WHO-PQ for imported IVDs is reasonable
- Improving public-private communication and relationships during regulatory matters and national procurement regulations

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